

# Science, Not Stigma: Perspectives on Blood Donor Controversy

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## Background<sup>1</sup>

After the emergence of the HIV/AIDS epidemic in the 1980s, gay and bisexual men were legally banned from donating blood in the United States due to misperceptions about the nature of HIV and the risk of HIV transmission from transfusions with blood from homosexual individuals. In 2015, the Food and Drug Administration replaced the ban with a 12-month “deferral period” for blood donation from men who have engaged in sexual activity with other men (MSM). However, the 12-month deferral period still implies an *effective* ban for MSM, unless they stop living their lives freely. The only way for MSM to donate blood is to cease sexual activity for 1 year, which is inconsistent with established science about HIV and with social progress. This state of affairs hinges mainly on inadequate screening criteria for blood donations that focus on incorrect assumptions when probing potential donors for HIV risk. Such screening criteria are not only discriminatory, but also inconsistent with many aspects HIV science, e.g. risk modeling, transmission dynamics, and

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<sup>1</sup> This paper is a research summary written in conjunction with the Blood Equality campaign against blood donor discrimination in the United States ([www.bloodequality.com](http://www.bloodequality.com)). It summarizes key findings and insights gleaned from a series of meetings with key players in blood donation including the American Association of Blood Banks, the U.S. Food & Drug Administration, and Gay Men's Health Crisis (GMHC), among others.

testing technology. Biotechnology plays an integral role in solving the blood ban problem at different junctures along the blood donor screening, blood collection, and bulk testing processes. Through my research this year with the Blood Equality campaign, we have worked to illuminate the central issues surrounding the blood donation crisis to its crucial stakeholders, brought together experts from science and policy to debate the issue, brainstormed possible solutions to the blood ban, and have begun to explore the feasibility of some solutions at a local level. This report summarizes our efforts, their results, their implications, and future directions. In short, my research with the medical branch of the campaign has led to several key developments in the effort toward non-discriminatory donation policy, and we are poised to continue making impacts into the future.

### **Systematic Discrimination and Sexual Behavior**

Current blood donation policy in the United States unfortunately permits systematic, legal discrimination of blood donors based on sexual orientation, specifically through the discarding of blood samples received from bi- or homosexual men. Supporters of the standing blood policy cite the safety of the blood supply as a critical concern for changing policy, yet also cite problems with blood shortages and express a desire for scientifically sound blood donor screening schema. As such, their perspective harbors an inherent contradiction, since much scientific and medical literature shows the mechanism and risk of HIV infection to be independent of sexual orientation and contingent on specific sexual behaviors.

Engaging in certain sexual acts without condoms or other barrier-method protection is a driving factor in measuring HIV risk by behavior. For instance, heterosexual couples engaging in anal sex are at high risk for HIV transmission events independently of the heterosexuality of the relationship (Duby 2015), and circumcision status can have an impact on HIV risk in heterosexual

couples (Seigfried 2009). Therefore, some of the most high-risk individuals may not be MSM. As such, there is no factual basis for discriminatory blood policy in the United States or elsewhere, as the virology and transmission of HIV is agnostic to sexual preference and heavily dependent on behavior. Thus, motion to rethink and replace the blood donation policy in the U.S. in light of socially progressive values is imperative if our legislation is to reflect contemporary American values.

## **International Precedent**

The regularly advanced “safe and adequate blood supply” argument in the blood quality space entails that the chance for transmission of HIV from donor blood must be the same or less than the current rate of risk without MSM donations, else there is no immediate imperative to change policy. However, this argument assumes an increased risk of transmission from homosexual blood, which has no basis in medical science and is refuted by international action on such policies —other countries have changed their blood policies to allow MSM donations without ill effect on the adequacy or safety of their national blood supplies. Italy is a world leader in this regard, finding that moving from MSM deferral to individual risk assessment does not result in a disproportionate increase in HIV seropositive donors who are MSM.

When comparing the period before and after the implementation of individual risk assessment policy in 2001, no significant increase in the proportion of men who have sex with men compared to heterosexuals was observed among HIV antibody-positive blood donors. (Suligoi 2013) This suggests that the change in donor deferral policy did not lead to a disproportionate increase of HIV-seropositive men who have sex with men. Moreover, it was also found in follow-up studies that the majority of HIV+ donors who engaged in at-risk behaviors proximate to blood donation are heterosexual and unaware of their HIV status. (Raimondo 2016) These donors were unaware that

they were engaging in at-risk behavior, underscoring the need for better public education about HIV and at-risk behaviors. Taken together, these studies and their implications provide adequate precedent and reason for moving toward an individual risk assessment paradigm in the United States, thus eliminating the discrimination inherent in today's standing policy.

### **Screening Technology and Transmission Risk Modeling**

In the past, HIV infection was detected through the presence of antibodies to the virus in blood, relying solely on the presence of immune response. Such methods were inadequate and therefore improved, as there are latent phases in HIV infection during which there is virus in the blood but no antibody response. To combat this problem, nucleic acid amplification testing (NAT) has become the new norm for HIV detection in blood, and newer, more sensitive methods have been investigated in conjunction with new transmission risk models. These new screening methods reduce the virus transmission risk in the window period by 54% to 58% compared to older methods using NAT, while the incremental risk caused by releasing donations with duplicate NAT tests results is 5% to 6%. (Weusten 2011) Therefore, maximum safety of the blood supply can feasibly be achieved through the implementation of repeat NAT testing algorithms at blood collection and supply centers.

Many arguments against lifting MSM blood donation bans cite the increased risk reported by various modeling schemes for blood transfusion (Yang 2016), however other studies contradict this notion. For instance, it has been reported and argued that modeling methods used to predict transmission risk over-estimate actual risk, and that MSM donations confer zero risk to donation recipients. (Germain 2016, O'Brien 2016, Custer 2016) As such, there is now more than adequate technology to detect HIV in blood donation through bulk NAT, and risk of transmission from

MSM donations has been over estimated compared to heterosexual donation. This suggests that policy should change to allow MSM donations based on the latest scientific understanding of transmission risk and current screening capabilities.

## **Advisory Boards**

A large part of our research consisted in preparing for and assembling two Blood Equality Medical Advisory Board. These advisory boards brought together experts in HIV virology, public policy, gay rights, law, and major figures from the United States government and blood donation industry. Unexpectedly, these meetings were the first of their kind according to attendees—the issue has certainly been discussed within these experts' respective fields, however they had never come together in a workshop format to discuss and exchange ideas. Participants in our advisory board commended us on organizing such a gathering with the bold objective of aligning disparate individuals and holding an open forum.

Through our advisory boards, it became clear who they key players in the MSM blood donor controversy and their respective positions. The blood collection and banking industry falls on the more conservative side of the debate for largely practical reasons derived from their responsibility to ensure recipient safety. In short, they seem to understand the drive to change donor screening policy, however they are reluctant because there are not large-scale, government-sponsored trials or studies testing the various hypotheses about transmission risk from MSM blood samples. Opposite the blood collection industry are LGBT activist groups and similar organizations. The driving force behind their position is discrimination. From their perspective, current screening practices' exclusion of MSM donors is blatantly discriminatory, especially in light of the scientific incongruences discussed above.

At center and left of center, we find the FDA and HIV experts, respectively. The federal government expresses full understanding of the argument for policy change, and is willing to explore steps forward to change it. However, the rate-limiting step is funding and time. In order to enact a policy change, the federal government claims that large scale studies must be done the United States (like those conducted in Italy) to demonstrate zero increased risk to blood recipients. HIV experts and other scientists largely hold an aggressively pro-change policy. They understand they rate-limiting factors of conducting large scale studies, but find no solace in the government's reluctance to get such studies funded and underway given the evidence that current policy is scientifically unsound.

### **Donor Screening Criteria**

The two advisory boards we held had related objectives, and were intertwined with the submission of a public comment to the FDA regarding our support for change in blood donor policy at the federal level. The target of the first advisory board was the Donor History Questionnaire (DHQ item 34, Appendix A). In our view, the DHQ is the source of the discriminatory nature of blood policy. The single screening question that grounds the entire controversy asks, if the potential donor is a male, if they have had sexual contact with another male in the last 12 months. In the case of MSM, the answer to this single question leads to a discarded sample of blood. In our first advisory board, we discussed the problematic language as the driver for discrimination, recommending that the language be changed or survey methods be updated to take into account up-to-date science, screening methods, and ethics.

After our first advisory board, we submitted a comment to the FDA via public docket on the discriminatory nature of blood donation policy and the need for change (Appendix B). In short, our

view presses for the need for change in this area of policy, and some considerations and suggestions for the path forward. In our comment, we assert the problematic nature of the current donor questionnaire, and possible social scientific and empirical approaches toward policy change. After our submission of the document, we experienced much openness and collaborative attitudes from those in the blood collection industry, FDA, and scientific community. We were able to hold meetings with all these stakeholders, including the American Association of Blood Banks (AABB), Center for Biologics Evaluation and Research (CEBR), New York City Department of Health, and MIT/Broad Institute. Our interactions with these parties were instrumental in developing deeper understanding of all aspects of the debate, as well as the efforts to start getting empirical studies off the ground.

### **Public Docket Output**

These discussions provided the impetus for a second, more focused advisory board to discuss the responses to the public docket with the FDA, blood collection industry and select individuals from local health authorities and academia. Over all, the FDA continued its open attitude toward change.

In general, comments to the public docket express that the necessary path forward is toward individual risk assessment, with immediate inclination to at least decrease the deferral period to something harmonious with HIV infection dynamics, e.g. 3 months. They also express a need for expanded and enriched donor education programs to improve public understanding of HIV risk, at-risk behaviors, and other aspects of transmission. In regard to NAT, the commenters highlighted the need to invest in the improvement and further development of these technologies and the need to modernize blood-screening workflows. Other positions include a need for transparency on progress

—without this, the public remains less aware of the government’s actual position on the issue, and may misconstrue their position. Constant communication with the public will thus be key.

Most commenters agreed that any changes to the DHQ need to be vetted and ensured to be comprehensible for the full spectrum of possible blood donors so that the actual information being sought by survey questions is captured. Most of all, comments asserted that any deferral period should be based on the knowledge and information of the prospective donor and subsequent empirical testing, and not *prima facie* on the donor’s sexual orientation or gender identity (nor that of their partner/s), or perceived monogamy.

In response to the public docket submissions, the FDA arrived at a set of more next steps, as well as general principles for the path forward on the blood donation controversy. Practically, they will be focused on continuing to monitor the Transfusion-Transmissible Infection Monitoring System (TTIMS) for changes in HIV incidence and risk factor correlations in order to get a better grasp on the current epidemiology of HIV and its relation to donated blood and particular populations. This keeps perceptions of risk in line with science rather than assumptions about specific populations of individuals based on sexual orientation or gender identity. Further next steps include development and validity testing for individual risk assessment paradigms and tools, as well as getting operational pilots for individual risk assessment instruments off the ground.

In terms of general principles, the FDA takes up a dual aspect position on the path forward toward non-discriminatory policy: a laboratory science track and a social science track. In the former, they plan to investigate technological means to improve blood-testing procedure through feasibility studies of NAT and pathogen inactivation. In the latter, they plan to focus on improving and augmenting donor education and revision/testing of new language and formats for the DHQ. Across both tracks, they hope to maximize transparency through stakeholder engagement and public advisory committees.

## **Biotechnological Solutions**

A number of key considerations in the blood donor controversy debate have technological solutions, or at least aspects that can be better investigated through the use of informatics and diagnostic/detection technology.

### Informatics

Revising and vetting new DHQ language is the province of the FDA and the American Association of Blood Banks, however there is good reason for additional exploration of related empirical questions about survey instruments and other informatic variables, structures, and techniques. First of these is the use of print versus digital technology in screening procedures. Critically, movement to digital formats with databases and live monitoring open the door to large-scale quantitative analysis on qualitative responses to survey questions that can be stratified by a plethora of different variables, including age, sex, and behavior, and (in conjunction with NAT data) HIV status.

Such data computation is a robust platform for beginning to reveal associations between material variables important to the safety of the blood supply (i.e. presence of virus) as well as less concrete associations among behavior, relative risk, and HIV status. For instance, such architecture allows for quantitative answers to questions like, “How many donors who answered X questions as YES, are also HIV+?” With enough data behind them, such answers would be grounded in science and objectivity, rather than assumptions and possibly mistaken perceptions about blood donors based on sexual orientation, gender identity or other aspects.

Of course, there are challenges to an informatics approach to blood donor screening. First, the creation of a nationally accessible database system for collecting, storing, and analyzing data is a challenge. On the donor side, the accessibility of survey format and the effectiveness of survey questions are always looming variables. For instance, would it be more effective to collect all the same data from all the same questions from all donors, or would it be more fruitful to develop a personalized response system that selectively asked “branched” questions dependent on donors’ prior responses to prior questions? Both have their merits. The former puts all collected data on the same plane, making for perhaps easier analysis on multiple variables, and may reveal surprising associations between, for example, blood donor HIV status and geography. The latter probes more deeply into individual donor history, however the branched informatics structure may introduce difficulty in donor-wide association analyses (e.g. to HIV status). In either case, much can be learned from the genomics space, particularly from large genome-wide association studies with behavioral variables (Okbay 2016) and reflexive data sets (Pickrell 2016), and the mapping of genomic gradients onto geography to capture continuities across space (Serr 2004).

### Diagnostic Technology

The blood donor controversy leans heavily on perceptions about the HIV status of potential donors at blood collection sites and the danger of an HIV+ blood sample being given to a blood recipient. In addition to NAT (which could be implemented in large-scale screening), point-of-care (POC) HIV testing could provide a first line solution for protecting blood recipients and keeping the blood supply safe. Moreover, there is precedent for HIV quick testing in non-laboratory settings—including bars, clubs, and other locations—so it is certainly plausible to deploy such technologies at blood collection centers across the country.

At present, HIV quick testing has advanced such that store-bought antibody-based kits can deliver results within 30 minutes. (CDC 2017, NAM 2017) Such kits have been suggested as solutions for resource impoverished settings for their quickness and compatibility with the dynamics of care in resource-limited environments such as sub-Saharan Africa. (Stevens 2014, Guo 2015) In blood collection centers, this implies that workers could feasibly integrate HIV quick testing into their blood collection process. Practically speaking, this would entail some training or perhaps including a diagnostic specialist on-site, but such logistical issues could easily be overcome in light of the safety benefits conferred by instituting POC technology in blood screening procedures. Integrating POC testing at collection sites can also add an objective measure to the qualitative survey responses currently solicited by the DHQ, suggesting that it may be a viable interim solution while larger changes to the DHQ are discussed.

With point-of-care testing, the blood collection industry has a real opportunity to quickly abandon discriminatory practices for scientifically sound methods. For instance, if POC testing is implemented, the DHQ can still *ask* about MSM behavior, but deterring the acceptance or refusal of a blood sample can be based on a quick test instead of a behavioral assumption grounded in misperceptions about HIV risk. Furthermore, quick testing technology has now been integrated with smartphones (Guo 2015), suggesting even more possibilities for fast and effective first-line protection against HIV+ blood samples.

## **Discussion and Future Directions**

Although my time for Supervised Research has come to a close, I will be continuing my work with Blood Equality. In particular, we are now currently working to meet with local stakeholders to discuss the informatics and biotechnological solutions offered in the preceding

section, with hopes to get a pilot study off the ground. In particular, we are working to align with the NYC Department of Health, a strong supporter of non-discriminatory blood screening policy. Moving forward, we hope to present the arguments and research discussed above as evidence for the plausibility of empirical studies that demonstrate local solutions to the larger blood equality problem. That is, if we can show that informatics and biotechnology can remove the discriminatory quotient from blood screening and collection, this is fantastic evidence for scaling up efforts to the national level. On its face, the MSM blood donor controversy represents a vestige of scientifically uninformed policy, however it signals a grand opportunity for a necessary step forward in the advancement of human rights through advocating for change, doing good science, and using technology to dissolve outdated discriminatory practices in our country.

## Appendix A

### Full-length Donor History Questionnaire (DHQ)

### Full-Length Donor History Questionnaire

	Yes	No	
Are you			
1. Feeling healthy and well today?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Currently taking an antibiotic?	<input type="checkbox"/>	<input type="checkbox"/>	
3. Currently taking any other medication for an infection?	<input type="checkbox"/>	<input type="checkbox"/>	
Please read the Medication Deferral List.			
4. Are you now taking or have you ever taken any medications on the Medication Deferral List?	<input type="checkbox"/>	<input type="checkbox"/>	
5. Have you read the educational materials?	<input type="checkbox"/>	<input type="checkbox"/>	
In the past <b>48 hours</b>			
6. Have you taken aspirin or anything that has aspirin in it?	<input type="checkbox"/>	<input type="checkbox"/>	
In the past <b>6 weeks</b>			
7. Female donors: Have you been pregnant or are you pregnant now? (Males: check "I am male.")	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> I am male
In the past <b>8 weeks have you</b>			
8. Donated blood, platelets or plasma?	<input type="checkbox"/>	<input type="checkbox"/>	
9. Had any vaccinations or other shots?	<input type="checkbox"/>	<input type="checkbox"/>	
10. Had contact with someone who had a smallpox vaccination?	<input type="checkbox"/>	<input type="checkbox"/>	
In the past <b>16 weeks</b>			
11. Have you donated a double unit of red cells using an apheresis machine?	<input type="checkbox"/>	<input type="checkbox"/>	
In the past <b>12 months have you</b>			
12. Had a blood transfusion?	<input type="checkbox"/>	<input type="checkbox"/>	
13. Had a transplant such as organ, tissue, or bone marrow?	<input type="checkbox"/>	<input type="checkbox"/>	
14. Had a graft such as bone or skin?	<input type="checkbox"/>	<input type="checkbox"/>	
15. Come into contact with someone else's blood?	<input type="checkbox"/>	<input type="checkbox"/>	
16. Had an accidental needle-stick?	<input type="checkbox"/>	<input type="checkbox"/>	
17. Had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?	<input type="checkbox"/>	<input type="checkbox"/>	
18. Had sexual contact with a prostitute or anyone else who takes money or drugs or other payment for sex?	<input type="checkbox"/>	<input type="checkbox"/>	
19. Had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything <u>not</u> prescribed by their doctor?	<input type="checkbox"/>	<input type="checkbox"/>	
20. Had sexual contact with anyone who has hemophilia or has used clotting factor concentrates?	<input type="checkbox"/>	<input type="checkbox"/>	
21. Female donors: Had sexual contact with a male who has ever had sexual contact with another male? (Males: check "I am male.")	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> I am male
22. Had sexual contact with a person who has hepatitis?	<input type="checkbox"/>	<input type="checkbox"/>	
23. Lived with a person who has hepatitis?	<input type="checkbox"/>	<input type="checkbox"/>	
24. Had a tattoo?	<input type="checkbox"/>	<input type="checkbox"/>	
25. Had ear or body piercing?	<input type="checkbox"/>	<input type="checkbox"/>	

**Full-Length Donor History Questionnaire**

	Yes	No
26. Had or been treated for syphilis or gonorrhea?	<input type="checkbox"/>	<input type="checkbox"/>
27. Been in juvenile detention, lockup, jail, or prison for more than 72 hours?	<input type="checkbox"/>	<input type="checkbox"/>
<b>In the past <u>three years</u> have you</b>		
28. Been outside the United States or Canada?	<input type="checkbox"/>	<input type="checkbox"/>
<b>From 1980 through 1996,</b>		
29. Did you spend time that adds up to three (3) months or more in the United Kingdom? (Review list of countries in the UK)	<input type="checkbox"/>	<input type="checkbox"/>
30. Were you a member of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military?	<input type="checkbox"/>	<input type="checkbox"/>
<b>From 1980 to the present, did you</b>		
31. Spend time that adds up to five (5) years or more in Europe? (Review list of countries in Europe.)	<input type="checkbox"/>	<input type="checkbox"/>
32. Receive a blood transfusion in the United Kingdom or France? (Review list of countries in the UK.)	<input type="checkbox"/>	<input type="checkbox"/>
<b>From 1977 to the present, have you</b>		
33. Received money, drugs, or other payment for sex?	<input type="checkbox"/>	<input type="checkbox"/>
34. Male donors: had sexual contact with another male, even once? (Females: check "I am female.")	<input type="checkbox"/>	<input type="checkbox"/>
<b>Have you EVER</b>		
35. Had a positive test for the HIV/AIDS virus?	<input type="checkbox"/>	<input type="checkbox"/>
36. Used needles to take drugs, steroids, or anything <u>not</u> prescribed by your doctor?	<input type="checkbox"/>	<input type="checkbox"/>
37. Used clotting factor concentrates?	<input type="checkbox"/>	<input type="checkbox"/>
38. Had hepatitis?	<input type="checkbox"/>	<input type="checkbox"/>
39. Had malaria?	<input type="checkbox"/>	<input type="checkbox"/>
40. Had Chagas' disease?	<input type="checkbox"/>	<input type="checkbox"/>
41. Had babesiosis?	<input type="checkbox"/>	<input type="checkbox"/>
42. Received a dura mater (or brain covering) graft?	<input type="checkbox"/>	<input type="checkbox"/>
43. Had any type of cancer, including leukemia?	<input type="checkbox"/>	<input type="checkbox"/>
44. Had any problems with your heart or lungs?	<input type="checkbox"/>	<input type="checkbox"/>
45. Had a bleeding condition or a blood disease?	<input type="checkbox"/>	<input type="checkbox"/>
46. Had sexual contact with anyone who was born in or lived in Africa?	<input type="checkbox"/>	<input type="checkbox"/>
47. Been in Africa?	<input type="checkbox"/>	<input type="checkbox"/>
48. Have any of your relatives had Creutzfeldt-Jakob disease?	<input type="checkbox"/>	<input type="checkbox"/>

**Appendix B**

**Public Comment on Blood Donor Deferral Policy**



**Docket FDA-2016-N-1502**  
**Public Comment on Blood Donor Deferral Policy**

**To:** United States Food and Drug Administration, Department of Health and Human Services  
**From:** Blood Equality Initiative  
**Re:** Docket FDA-2016-N-1502: Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Establishment of a Public Docket; Request for Comments

**I: General considerations for progressive blood donation policy**

We would like to thank the experts on blood, virology, blood donation, government, policy, and medicine who joined us for our BLOOD EQUALITY MEDICAL ADVISORY BOARD earlier this year. We appreciate their counsel and suggestions, which helped to guide us in this submission. *We submit the following comment in support of alternate deferral options, specifically individual risk assessment:*

The 2015 revision to the blood donation ban on MSM marked an important step forward in the United States. However, under the current 1-year celibacy deferral, thousands of much-needed pints of blood are still never drawn. Considering the current state of HIV testing, the epidemiology of transmission, and policy advances seen around the world, there is still much to be done.

Our group identified several major themes to consider, including scientific evidence, survey design, viral detection/quantification biotechnology, and risk assessment. We suggest a rapid path forward toward individual risk assessment via interim evidence-based decreases in deferral periods for blood donors. In order to realize this change, we also suggest ideas be explored around individual risk assessment and its implementation. It is our view that the following groups of ideas could help generate momentum toward the goal of a safe and equitable blood donation policy:

Investigative-scientific	Social-political
<ul style="list-style-type: none"><li>Further studies in viral window period biology and nucleic acid testing that quantify risk across ALL donors</li><li>Continued support and funding for the use and implementation of NAT in blood centers</li><li>Funding for the development of pathogen reduction biotechnology</li><li>Statistical and epidemiological studies of HIV transmission in MSM and other populations considering geography, behavior, transmission, and statistical mapping</li></ul>	<ul style="list-style-type: none"><li>Consider revisions to the Donor History Questionnaire:<ul style="list-style-type: none"><li>Consider time-based questions in probing for behavioral information for ALL donors</li><li>Clear definitions of more specific "at-risk" behaviors for ALL donors</li><li>Real-world impact of individual risk assessments and risk model predictions</li><li>Consider immediate pilot studies of new survey questions/formats</li></ul></li></ul>

**II: Conceptual considerations for changes to the Donor History Questionnaire**

**A. The effectiveness of time-based questions in probing behavior, donor perception, and recall**

In light of today's understanding of viral window periods, it may prove helpful to reconsider what time periods provide the most rational boundaries from a scientific perspective. This includes refinement of window periods based on nucleic acid testing and repeat test algorithms.

- For example, deferral periods on the order of weeks rather than months, as modern technologies can accurately detect virus within a period of weeks post-exposure



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**B. The nature of sexual behavior, clarity of specific acts, and their relation to risk for ALL donors**

The nature of sexual behavior and specific sexual acts should be considered as they relate to transmission risk for all donors.

- For example, a *gradient of risk* by behavior across all donors could be made explicit and improve question design: Injection drug use vs. anal sex with multiple partners vs. unprotected or protected anal sex in monogamous relationship vs. penile-vaginal sex. Each of these can be assessed to guide equitable question design and deferral parameters.
- Most risk behaviors are more closely linked to specific body parts and types of sexual contact, as opposed to gender or sexual identity; questions should reflect this.

**C. The effectiveness of survey questions in probing for meaningful risk associations**

Clearer donor survey questions that consider a gradient of risk by behavior for all donors may help ameliorate the ambiguity about a donor's sexual and behavioral history, and help clarify self-reported level of risk with the goal of improving donor evaluation accuracy.

- Natural language analysis, linguistics, and social science may reveal new areas worthy of exploration or short-term pilot programs.

**III: Immediate Actions**

As the complex matrix of approaches is evaluated to move toward individual risk assessment for ALL donors, we recommend quickly revising the 1-year celibacy deferral. The FDA should feel confident and quickly move to a shorter window that reflects today's scientific knowledge.

**Conclusion**

Science and policy are only effective insofar as people understand them. Public transparency, donor education, and clear communication are pivotal for progress. We believe that consideration and exploration of the above areas help point a way forward. The suggestions offered above refrain from micro-level specifics—we entrust this to the scientists at the FDA, NIH, and CDC as well as a range of scientific collaborators. The intent of this submission is to help articulate key areas to consider and explore as the FDA considers a thoughtful and fair blood donation policy for ALL donors. To that end, we embrace, and look forward to, further collaboration focused on this goal. Thank you for your consideration.

**STATEMENT BY GMHC CEO KELSEY LOUIE:**

*"We were encouraged by the fact that the FDA solicited public comments on potential changes to the current blood donation policy for men who have sex with men. With the comment period over, the real work must begin. GMHC is calling on the FDA to explore the alternate deferral options that have been submitted in the form of comments over the past four months, such as individual risk assessment, which is based on donor activity, not identity. Part of this work means evaluating current blood testing technologies. We also ask that the FDA explore various activities and the variety of risk levels they pose, such as the consistent use of PrEP and condoms.*

*At a time when the LGBT community feels increasingly marginalized, the FDA must make altering the policy a top priority. Now is the time for our nation to move forward from the current one-year deferral policy, which ignores the modern science of HIV-testing and perpetuates the discrimination we have been fighting for over 35 years."*



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